K063868
p1 of 2

NIPRO MEDICAL CORPORATION
3150 N.W. 107 Avenue
Miami, Florida 33172
Tel.: (305) 599-7174
Fax: (305) 599-8454

FEB 5 2007

510(k) Summary of Safety and Effectiveness for NIPRO BioHole™ Needle

807.92(a)(1)

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: October 24, 2006

807.92(a)(2)

Trade Name: NIPRO BioHole™ Needle
Common Name: AVF Needle
Classification Name: Blood access Device and Accessories (21 CFR 876.5540)
Product Code: 78 FIE

807.92(a)(3)

Legally marketed substantial equivalent device:
NIPRO AVF Needle (K955182)
Medisystems ButtonHole Needle Set (K990803)

807.92(a)(4)

Description of device:
The NIPRO BioHole™ Needle is a sterile, single-use device that consists of a hollow, winged needle, a flexible tube, mini clamp and locking connector. This device is provided in four design types: fixed wing type A, turnable wing type A, fixed wing type B, turnable wing type B. Needles are available in two lengths, 1" and 1¼", as well as four gauges (14-17), with and without back eye. The flexible tubing comes in lengths of 150mm and 300mm. The NIPRO BioHole™ Needle is packaged individually in a plastic pouch with paper backing, which contains labeling that adequately defines indications for use and warnings.

These devices operate on the principles of a blood access device. They are sterile, single use only, non-toxic and non-pyrogenic.

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807.92(a)(5)

Indications for Use:
The NIPRO BioHole™ Needle is intended for use as a blood access device for dialysis procedures using a constant-site cannulation technique of needle insertion with an established, mature constant-site also known as a buttonhole access site.

807.92(a)(6)

Comparison of technological characteristics:
The NIPRO BioHole™ Needle is substantially equivalent to the Medisystems Buttonhole Needle Set (K990803) in terms of indications for use, labeling, and overall performance characteristics. It is identical to the NIPRO AVF Needle in terms of materials of construction.

807.92(b)(1)

Non-clinical tests submitted:
Performance testing was conducted to verify that the device is safe and effective for its intended use. Those reports along with associated data are included in this submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:
The results of the performance testing and the comparison of technological characteristics demonstrate that the NIPRO BioHole™ Needle performs equivalent to the predicate devices and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB - 5 2007

Ms. Jessica Oswald
Regulatory Affairs Specialist
Nipro Medical Corporation
3150 NW 107th Avenue
MIAMI FL 33172

Re: K063368
NIPRO BioHole™ Needle
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: November 4, 2006
Received: November 7, 2006

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K063368

Device Name: NIPRO BioHole™ Needle

Indications for Use:

The NIPRO BioHole™ Needle is intended for use as a blood access device for dialysis procedures using a constant-site cannulation technique of needle insertion with an established, mature constant-site also known as a buttonhole access site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

David R. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063368